JUL - 3 2006

510(k) Summary

Ortho-Clinical Diagnostics
a Johnson & Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K060480.

1 Submitter Name, Address and Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4131

Contact Person: Leah Van De Water

2 Preparation Date

Date 510(k) prepared: February 22, 2006

3 Device Name

VITROS Immunodiagnostic Products Cortisol Reagent Pack
Common Name: Cortisol Reagent Pack
Classification Name: Cortisol(Hydrocortisone and Hydroxycorticosterone) Test System (862.1205), Class II

VITROS Immunodiagnostic Products Cortisol Calibrators
Common Name: Cortisol Calibrators
Classification Name: Calibrator (862.1150), Class II

VITROS Immunodiagnostic Products NT-proBNP Metabolism Controls
Common Name: Metabolism Controls
Classification: Quality control material (862.1660), Class I

4 Predicate Device

The VITROS Immunodiagnostic Products Cortisol Assay is substantially equivalent to the VITROS Immunodiagnostic Products Cortisol Assay (K983990-original formulation). The only modifications made to the proposed VITROS Immunodiagnostic Products Cortisol Assay are to the VITROS Immunodiagnostic Products Cortisol Reagent Pack. There are **no** modifications being made to the VITROS Immunodiagnostic Products Cortisol Calibrators or the VITROS Immunodiagnostic Products Metabolism Controls, which were previously cleared under K983990.

5 Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of there main elements:

- The VITROS Immunodiagnostic Products range of immunoassay products in this case VITROS Immunodiagnostic Products Cortisol Reagent Pack, VITROS Immunodiagnostic Products Cortisol Calibrators (cleared under K983990) and VITROS Immunodiagnostic Products Metabolism Controls (cleared under K983990), which are combined by the VITROS Immunodiagnostic System to perform the VITROS Cortisol assay.

- The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

- Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

Note: High Sample Diluent B was cleared as part of the VITROS Immunodiagnostic Products Total ß-hCG Reagent Pack and VITROS Immunodiagnostic Products Total ß-hCG Calibrators 510(k) premarket notification (K970894).

The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

6 Device Intended Use

VITROS Immunodiagnostic Cortisol Reagent Pack

For the *in vitro* quantitative measurement of cortisol in human serum, plasma (heparin or EDTA) or urine.

VITROS Immunodiagnostic Products Cortisol Calibrators

For the *in vitro* use in the calibration of the VITROS Immunodiagnsotic System for the quantitative measurement of cortisol in human serum, plasma (heparin or EDTA) or urine.

VITROS Immunodiagnostic Products Metabolism Controls

For the *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the measurement of cortisol in human serum, plasma (heparin or EDTA) or urine.

7 Comparison to Predicate Device

The VITROS Immunodiagnostic Products Cortisol Reagent Pack is substantially equivalent to VITROS Immunodiagnostic Products Cortisol Reagent Pack (K983990) cleared by the FDA for *in vitro* diagnostic use.

Table 1 lists the characteristics of the VITROS Cortisol Reagent Pack (new formulation) and the VITROS Cortisol Reagent Pack (K983990-original formulation). There are **no** modifications to the current VITROS Immunodiagnostic Products Cortisol Calibrators (cleared under K983990), and VITROS Immunodiagnostic Products Metabolism Controls (cleared under K983990).

Table 1 List of VITROS Cortisol Reagent Pack Characteristics: Comparison to Predicate Device

Device Characteristic	Predicate Device VITROS Cortisol Reagent Pack (K983990-Current)	New Device VITROS Cortisol Reagent Pack (Modified)
Reportable Range	0 to 1700 nmol/L	4.39 to 1700 nmol/L
Sample type	Serum, plasma (EDTA or heparin) or urine.	Serum plasma (EDTA or heparin) or urine.
Biotinylated Antibody Reagent	**Antibody** Sheep polyclonal anti-cortisol antibody biotinylated antibody reagent (pool of two bleeds from a single sheep immunized in-house at Pollards Wood) **Concentration of Antibody** 1.5 mg/Kg	**Antibody** Sheep polyclonal anti-cortisol antibody biotinylated antibody reagent (pool of eight bleeds from two sheep immunized in-house at Pollards Wood) **Concentration of Antibody** 0.5 mg/Kg
HRP Conjugate Reagent	Contains Bovine Alpha Globulin	Removed Bovine Alpha Globulin Added ANS (8-anilino-1-napthalenesulfonic acid) to correct for azide
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample volume	25µL	25µL
Incubation time and temperature	30 minutes at 37°C	30 minutes at 37°C

10 Conclusions

The information presented in the pre-market notification demonstrates that the performance of the proposed VITROS Immunodiagnostic Products Cortisol Assay is substantially equivalent to the cleared predicate device.

Equivalent performance was demonstrated using manufactured reagents, positive and negative controls and testing human samples throughout the assay range.

The information presented in the premarket notification provides a reasonable assurance that the proposed VITROS Cortisol Assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Leah Van De Water
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Dr.
Rochester, NY 14626-5101

Re: k060480
Trade/Device Name: VITROS Immunodiagnostic Products Cortisol Reagent Pak
VITROS Immunodiagnostic Products Cortisol Calibrator
VITROS Immunodiagnostic Products Metabolism Controls
Regulation Number: 21 CFR§862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: CGR, JIS, JJX
Dated: June 16, 2006
Received: June 19, 2006

Dear Ms. Water:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT B

Indications for Use

510(k) Number (if known): K060490

Device Name:

VITROS Immunodiagnostic Products Cortisol Reagent Pack
VITROS Immunodiagnostic Products Cortisol Calibrator
VITROS Immunodiagnostic Products Metabolism Controls

Indications for Use:

The measurement of cortisol in human serum, plasma (heparin or EDTA) or urine aids in the assessment of adrenal status.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060490